

REMARKS

Claims 26, 33-36, 39-44 and 49 are presently pending. Of these, Claims 35 and 39-44 are withdrawn. Amendments to Claims 26 and 49 are supported by the Specification as filed, for example at page 11, lines 23-27, page 12, lines 9-15 and 19-25. Claims 37, 38, 45 and 46 are canceled in accordance with amendments to Claims 26 and 49. No new matter has been added herewith. The following addresses the substance of the Office Action.

Enablement

Claims 26, 33, 34, and 36 were rejected under 35 U.S.C. § 112, first paragraph with regard to enablement. The Examiner found that the Specification was enabling for a method for detecting the presence of a breast cancer cell in a subject or in a biological sample from said subject comprising screening for the level of an expression product of a polynucleotide comprising SEQ ID NO: 4 or a polynucleotide that encodes SEQ ID NO: 6, but does not reasonably provide enablement for other embodiments. Although Applicants do not necessarily agree with the Examiner's conclusion, in order to expedite prosecution, Applicants have amended the claims to limit them to those features that the Examiner has agreed are enabled. In view of these amendments, Claims 26, 33, 34, and 36 are in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph. Accordingly, the Applicants respectfully request that the rejection be withdrawn.

Anticipation

Claims 26, 33 34 and 36 were rejected under 35 U.S.C. § 102(b) as being anticipated by Rosen et al. (U.S. Patent Publication No. 2002/0052308). The Examiner maintains that Rosen et al. disclose a nucleic acid sequence that is 100% identical to the nucleotide sequence of SEQ ID NO: 4. In particular, Rosen et al. discloses SEQ ID NO: 143, a 1235 nucleotide sequence that comprises the presently claimed SEQ ID NO: 4, which is 876 nucleotides in length. Applicants have amended Claim 26 to recite a method that comprises screening a subject or biological sample from a subject for the level of an expression product of a polynucleotide consisting of a sequence selected from the group consisting of SEQ ID NO: 4 and a polynucleotide that encodes SEQ ID NO: 6. Similarly, Claim 49 is amended to recite the step of contacting a tissue from a subject or a biological sample with an antibody specific for a polypeptide consisting of an amino

acid sequence selected from the group consisting of SEQ ID NO: 5 and SEQ ID NO: 6. Thus, these claims now exclude sequences larger than the recited specific sequences

To be anticipatory under 35 U.S.C. § 102, a reference must teach each and every element of the claimed invention. *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379 (Fed.Cir. 1986). “[A]nticipation requires that all of the elements and limitations of the claim are found within a single prior art reference.” *See Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991). Rosen et al. discloses a 1235 nucleotide sequence but does not disclose a polynucleotide consisting of a sequence selected from the group consisting of SEQ ID NO: 4 and a polynucleotide that encodes SEQ ID NO: 6 or a polypeptide consisting of an amino acid sequence selected from the group consisting of SEQ ID NO: 5 and SEQ ID NO: 6.

Moreover, Rosen teaches away from the presently claimed methods at page 82, Table 3, approximately at lines 23-30. In particular, Rosen states that preferably excluded from the invention are one or more polynucleotides comprising a nucleotide sequence described by the general formula of a-b, where a is the start position and is any integer between 1 and 1221 of SEQ ID NO: 143, and b is an end position and is an integer of 15 to 1235. Rosen also teaches to exclude polynucleotides where b is greater than or equal to (a + 14). In the present case, the 876 nucleotides of SEQ ID NO: 4, as disclosed by the present application, line up with nucleotides 183 to 1058 of SEQ ID NO: 143 (Rosen et al.). Thus, the start position of SEQ ID NO: 4 with respect to SEQ ID NO: 143 of Rosen is “an integer between 1 and 1221” (i.e., a = 183). In addition, the end position of SEQ ID NO: 4 with respect to SEQ ID NO: 143 of Rosen is “an integer between 15 and 1235” (i.e., b=1058) and “b is greater than or equal to a+14” (i.e., b ≥ (183+14) = 197). Thus, Rosen et al. specifically teaches to exclude a polynucleotide consisting of the sequence of SEQ ID NO: 4 to detect cancer, and therefore teaches away from the claimed invention.

In view of the preceding remarks, the claimed subject matter is novel with respect Rosen et al. Moreover, since Rosen et al. teaches away from the claimed subject matter, the claims are also nonobvious in view of Rosen et al. Accordingly, the Applicants respectfully request that the rejection under 35 U.S.C. § 102(b) be withdrawn.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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